

R E M A R K S

- Claims 1-29 are currently pending.
- Claim 18 has been amended.
- Claims 1, 18, 21 and 24 are the pending independent claims.

Rejection of Claims 21, 24-27 and 29 under 35 U.S.C. 102(b)

Claims 21, 24-27 and 29 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,152,919 filed March 18, 1999 and issued November 28, 2000 to *Said I. Hakky* (hereinafter "*Hakky*"). Applicant respectfully traverses this rejection.

The present claimed invention in claim 21 describes a wound management system. A multi-lumen cannula is adapted to be disposed in a wound site. A fiber optic light distribution system is adapted to irradiate the wound site with light. One or more catheters are adapted to deliver a fluid to the wound site. One or more evacuation lines are adapted to remove fluid from the wound site.

The Applicant submits that *Hakky* does not disclose every element recited in claims 21, 24-27 and 29, as required by the M.P.E.P. Thus, *Hakky* cannot anticipate these claims.

Hakky describes a resectoscope for laser coagulation and cutting of prostatic or bladder tissue (Abstract). The combination of coagulating/cutting using the laser energy with further cutting by mechanical means allows the surgeon

to perform this procedure more quickly and efficiently, and permits retrieval of the resected tissue for pathological examination (Abstract). Applicant respectfully submits that contrary to the assertion in the Office Action, *Hakky* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in the present claimed invention. Rather, Figure 1 and column 3, lines 1-10 of *Hakky*, cited in the Office Action, merely describe a resectoscope including a fiber optic laser member. The laser member is used to "coagulate and cut the prostatic or bladder tissue" to remove "very large pieces of prostatic and bladder tissue" See e.g., *Hakky*, col. 3, lns 62-63 and lns 66-67. Applicant respectfully submits that nowhere in this passage, or elsewhere in *Hakky* is there any description of a wound site. Rather, *Hakky* is primarily concerned with a surgical site and at that surgical site, using a laser member to cut tissue. Additionally, the present claimed invention recites "a fiber optic light distribution system to irradiate the wound site with light." In the present invention, a patient has previously sustained a wound, such as decubitus, ischial and sacral ulcers that is to be healed. These large area chronic wounds require treatment to "maintain an inflammatory response that promotes tissue granulation with fewer dressing changes and lower cost." See e.g., pg. 4, lns. 31-32 of the specification. Light dosing is used in the treatment of these large area wounds. See e.g., pg. 34, ln. 30 of the specification. In light dosing, "the fiber optic light distribution system includes a plurality of optical fibers for delivering light to the wound site. See e.g., pg. 5, lns. 20-23 of the

specification. As claimed, this is not a surgical procedure. Applicant respectfully submits that using a laser to cut and remove tissue, as in *Hakky*, is wholly unlike the present claimed invention which uses a fiber optic light distribution system to irradiate the wound site with light to promote tissue granulation. Thus, *Hakky* neither discloses nor suggests "a fiber optic light distribution system to irradiate the wound site with light" as recited in claim 21 of the present invention and therefore does not disclose at least this element of claim 21. Accordingly, the Applicant respectfully submits that claim 21 is patentable over *Hakky* and respectfully requests that the rejection of claim 21 be withdrawn.

Claim 24 describes a method of treating a wound site. The features described in claim 24 are similar to those described in claim 21. Therefore, the arguments presented above with respect to claim 21 also apply to claim 24. Consequently, withdrawal of the rejection of claim 24 is respectfully requested. Similarly, claims 25-27 and 29, which depend from claim 24, are patentable for at least the same reasons.

Rejection of Claims 1, 3, 5-8, 10, 11, 13-22, 24-27 and 29 under 35 U.S.C. 102(b)

Claims 1, 3, 5-8, 10, 11, 13-22, 24-27 and 29 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,026,367 filed March 18, 1988 and issued June 25, 1991 to *Michael E. Leckrone et al.* (hereinafter "*Leckrone*"). Applicant respectfully traverses this rejection.

The present claimed invention in claim 1 describes a wound management system. A multi-lumen cannula is adapted to be disposed in a wound site. A fiber optic light distribution system is adapted to irradiate the wound site with light. One or more catheters are adapted to deliver a fluid to the wound site. One or more evacuation lines are adapted to remove fluid from the wound site. A light source is coupled to the fiber optic light distribution system, and is adapted to supply light to the fiber optic light distribution system. One or more fluid supplies are coupled to the one or more catheters, and are adapted to supply fluid to the one or more catheters. A vacuum system is coupled to the one or more evacuation lines, and is adapted to evacuate the one or more evacuation lines. A controller is coupled to the light source, the one or more fluid supplies and the vacuum system. The controller is adapted to employ the vacuum system to remove exudates from the wound site; employ the one or more catheters to deliver fluid to the wound site; and employ the light source to deliver at least one light dose to the wound site.

The Applicant submits that *Leckrone* does not disclose every element recited in claims 1, 3, 5-8, 10, 11, 13-22, 24-27 and 29, as required by the M.P.E.P. Thus, *Leckrone* cannot anticipate these claims.

Leckrone describes a laser angioplasty catheter, which enables "laser energy transmitted by an optical fiber or a bundle of optical fibers to be released from the distal end of the catheter to disintegrate or vaporize

obstructions within blood vessels such as plaque in coronary, femoral, and other arteries." See e.g., col. 1, lns. 19-23 of *Leckrone*. Applicant respectfully submits that obstructions within blood vessels, are not equivalent to the wound sites recited in the present claimed invention. Additionally, the present claimed invention recites "a fiber optic light distribution system adapted to irradiate the wound site with light." In the present invention, a patient has already sustained a wound, such as decubitus, ischial and sacral ulcers. These large area chronic wounds require treatment to "maintain an inflammatory response that promotes tissue granulation with fewer dressing changes and lower cost." See e.g., pg. 4, lns. 31-32 of the specification. Light dosing is used in the treatment of these large area wounds. See e.g., pg. 34, ln. 30 of the specification. In light dosing, "the fiber optic light distribution system includes a plurality of optical fibers for delivering light to the wound site. See e.g., pg. 5, lns. 20-23 of the specification. Applicant respectfully submits that using a laser to disintegrate or vaporize obstructions within blood vessels, as in *Leckrone*, is wholly unlike the present claimed invention which uses a fiber optic light distribution system to irradiate the wound site with light to promote tissue granulation. Thus, *Leckrone* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in claim 1 of the present invention and therefore does not disclose at least this element of claim 1. Accordingly, the Applicant respectfully submits that claim 1 is patentable over *Leckrone* and respectfully requests that the rejection

of claim 1 be withdrawn. Likewise, claims 3, 5-8, 10, 11 and 13-17, which depend from claim 1, are patentable for at least the same reasons. Claims 18, 21 and 24 include features similar to those described above with respect to claim 1 and are considered to be patentable for the reasons given above with respect to claim 1. Claims 19-20 which depend from claim 18, claim 22 which depends from claim 21 and claims 25-27 and 29 which depend from claim 24, are considered to be patentable for at least the same reasons.

Accordingly, for the reasons noted above, the Applicant submits that claims 1, 18, 21 and 24 are patentable over *Leckrone* and respectfully request that the rejection be withdrawn. Likewise, claims 3, 5-8, 10, 11, and 13-17 depend from claim 1, claims 19-20 depend from claim 18, claim 22 depends from claim 21, and claims 25-27 and 29 depend from claim 24, and are patentable for at least the same reasons.

Rejection of Claims 10, 11, 13-22, 24-27 and 29 under 35 U.S.C. 102(b)

Claims 10, 11, 13-22, 24-27 and 29 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,041,108 filed June 9, 1989 and issue August 20, 2001 to *Kenneth R. Fox et al.* (hereinafter "*Fox*"). Applicant respectfully traverses this rejection.

The Applicants submit that *Fox* does not disclose

every element recited in claims 10, 11, 13-22, 24-27 and 29, as required by the M.P.E.P.. Thus, *Fox* cannot anticipate these claims.

Claims 10, 11 and 13-17 are dependent on claim 1. Therefore, *Fox* cannot anticipate claims 10, 11 and 13-17 unless *Fox* also anticipates every element of claim 1, from which they depend. Applicant respectfully submits that *Fox* does not disclose every element recited in claim 1. Namely, *Fox* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in the present claimed invention. *Fox*, instead, describes a method of using pulsed laser energy to destroy the tissue of luminal occlusions, such as atheromatous plaque. (Abstract). Applicant respectfully submits that tissues of luminal occlusions, as described in *Fox*, are not equivalent to wound sites, as recited in the present claimed invention. Additionally, as described above, Applicant respectfully submits that using a laser to destroy the tissue of luminal occlusions, as in *Fox*, is wholly unlike the present claimed invention which uses a fiber optic light distribution system to irradiate the wound site with light to promote tissue granulation. Thus, *Fox* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in claim 1 of the present invention and therefore does not disclose at least this element of claim 1. Likewise, claims 10, 11 and 13-17, which depend from claim 1, are patentable for at least the same reasons.

Fox does not disclose each and every element recited in claims 18-20. As such, *Fox* cannot anticipate these claims. However, solely to expedite prosecution, Applicant has amended claim 18 merely to make explicit what was implicit before. Specifically, Applicant has amended claim 18 to recite a system which comprises, among other features "a controller coupled to the one or more fluid supplies and the vacuum system, and adapted to automatically: employ the vacuum system to remove exudates from the wound site; and employ the one or more catheters to deliver fluid to the wound site." Applicant respectfully submits that no new matter has been added by this amendment. Support for the amendment can be found throughout the specification, and specifically on page 8, lines 4-8; page 10, lines 11-12, 22-25; page 11, lines 10-14; and page 17, lines 1-4. The controller, for example, may set a predetermined time period for the vacuum system to periodically remove the exudates from the wound site. See e.g., pg. 11, lns. 11-14 of the specification. Additionally the controller may be set to have the catheters provide set dosages of liquids into a wound site. See e.g., pg. 10, ln. 31 to pg. 11, ln. 1 of the specification. The automated controller improves clinical efficacy, improves patient care and potentially saves millions of dollars annually. See e.g., pg. 2, lns. 7-10 of the specification. The *Fox* method and system are wholly concerned with the use of a laser to destroy tissue of luminal occlusions. The surgeon aims the laser beam to effectively destroy or penetrate atherosclerotic plaque. See e.g., col. 3, lns. 63-66 of *Fox*. Applicant respectfully submits that while *Fox* includes a suction

channel for suctioning fluids and an inflow channel for injecting fluids, these channels are attached to the surgical tool and used during the laser destruction/penetration of atherosclerotic plaque. See e.g., col. 7, lns. 57-65 of Fox. This is wholly unlike the present claimed invention, which is concerned with managing the treatment of a wound through a controller automatically employing a vacuum system and fluid delivery system. Nowhere in *Fox* in the passages cited in the Office Action, or elsewhere in *Fox* is there any teaching or suggestion describing "a controller coupled to the one or more fluid supplies and the vacuum system, and adapted to automatically: employ the vacuum system to remove exudates from the wound site; and employ the one or more catheters to deliver fluid to the wound site" as recited in claim 18 of the present invention and therefore does not disclose at least this element of claim 18. Likewise, claims 19-20, which depend from claim 18, are patentable for at least the same reasons.

Fox does not disclose each and every element recited in claims 21, 22, 24-27 and 29. As described above with respect to claim 1, *Fox* is silent regarding the disclosure of "a fiber optic light distribution system adapted to irradiate the wound site with light." This feature is also recited in independent claims 21 and 24. As such, *Fox* cannot anticipate these claims. Likewise, claims 25-27 and 29, which depend from claim 24, are patentable for at least the same reasons.

Accordingly, for the reasons noted above, the

Applicant submits that claims 1, 18, 21 and 24 are patentable over *Fox* and respectfully request that the rejection be withdrawn. Likewise, claims 10, 11 and 13-17 depend from claim 1, claims 19-20 depend from claim 18, claim 22 depends from claim 21 and claims 25-27 and 29 depend from claim 24, and are patentable for at least the same reasons.

Rejection of Claims 1, 9, 12, 21 and 28 under 35 U.S.C.

102(b)

Claims 1, 9, 12, 21 and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,651,783 filed December 20, 1995 and issued July 29, 1997 to *Michael Reynard* (hereinafter "*Reynard*"). Applicant respectfully traverses this rejection.

The Applicants submit that *Reynard* does not disclose every element recited in claims 1, 9, 12, 21 and 28, as required by the M.P.E.P.. Thus, *Reynard* cannot anticipate these claims.

Applicant respectfully submits that *Reynard* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in claim 1 of the present invention. *Reynard* instead describes a device attachable to surgical devices for intraocular surgery that provides a laser for simultaneously delivering illumination and intraocular tissue coagulation and ablation. See e.g., Col. 2, lns. 47-51 of *Reynard*. Applicant respectfully submits that

intraocular surgery, as described in *Reynard*, is not equivalent to treating a wound site, as recited in the present claimed invention. Additionally, as described above, Applicant respectfully submits that using a laser to remove intraocular tissue and illuminate the surgical area, as in *Reynard*, is wholly unlike the present claimed invention which uses a fiber optic light distribution system to irradiate the wound site with light to promote tissue granulation. Thus, *Reynard* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in claim 1 of the present invention and therefore does not disclose at least this element of claim 1. Likewise, claims 9 and 12, which depend from claim 1, are patentable for at least the same reasons.

Similarly, independent claim 21 includes similar features to those described above with respect to claim 1 and is considered to be patentable for at least the same reasons.

Claim 28 is dependent on claim 24. Therefore, *Reynard* cannot anticipate claim 28 unless *Reynard* also anticipates every element of claim 24, from which claim 28 depends. Applicant respectfully submits that *Reynard* does not disclose every element recited in claim 24. As described above, *Reynard* neither discloses nor suggests "a fiber optic light distribution system adapted to irradiate the wound site with light" as recited in claim 24 of the present invention and therefore does not disclose at least this element of claim 24. Likewise, claim 28, which

depends from claim 24, is patentable for at least the same reasons.

Accordingly, for the reasons noted above, the Applicant submits that claims 1, 21 and 24 are patentable over *Reynard* and respectfully request that the rejection be withdrawn. Likewise, claims 9 and 12 depend from claim 1, and claim 28 depends from claim 24, and are patentable for at least the same reasons.

Rejection of Claims 2, 4 and 23 under 35 U.S.C. 103(a)

Claims 2, 4 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,041,108 filed June 9, 1989 and issued August 20, 1991 to *Kenneth R. Fox* (hereinafter "*Fox*") in view of U.S. Patent No. 6,605,082 filed July 2, 2001 and issued August 12, 2003 to *Norihiko Hareyama et al.* (hereinafter "*Hareyama*"). The Applicant respectfully traverses the rejection.

Applicant submits that neither *Fox* nor *Hareyama*, either singularly or in combination, disclose or suggest all the features recited in claims 2, 4 and 23, as required by the M.P.E. P.. Thus, claims 2, 4 and 23 are patentable over these references.

In particular, as detailed above, *Fox* does not disclose or even suggest all the features recited in claims 1 and 21, the base claims from which claims 2, 4 and 23 depend. In addition, *Hareyama* does not overcome the previously noted shortcomings of *Fox*. Therefore, claims 2, 4 and 23 are not obvious over the cited references and the

Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

The Applicant believes all pending claims are in condition for allowance, and respectfully requests reconsideration and allowance of the same.

The Applicant does not believe any additional Request for Extension of Time is required but if it is, please accept this paragraph as a request for such an Extension of Time and authorization to charge the requisite extension fee to Deposit Account No. 04-1696.

The Applicant does not believe any other fees are due regarding this amendment. If any other fees are required, however, please charge Deposit Account No. 04-1696.

The Applicant encourages the Examiner to telephone Applicant's attorney should any issues remain.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Steven M. Santisi".

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